ESTIMATION OF LEAD EXPOSURE FROM WATER SOURCES FOR U.S. CHILDREN

OVERVIEW

Since 1994, the Office of Solid Waste and Emergency Response (OSWER) has recommended the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK model) as a risk assessment tool to support environmental cleanup decisions at lead-contaminated residential sites (U.S. EPA, 1994a, b). The IEUBK model uses data on the presence and behavior of environmental lead to predict a plausible distribution or geometric mean (GM) of blood lead (PbB) for a hypothetical child or population of children.[1] The relative variability of PbB concentrations around the GM is defined as the geometric standard deviation (GSD). The GSD encompasses biological and behavioral differences, measurement variability from repeat sampling, variability as a result of sample locations, and analytical variability.[2] From this distribution, the IEUBK model estimates the risk (*i.e.*, probability) that a child's or a population of children's PbB concentration will exceed a certain level of concern (U.S. EPA, 1994a; White et al., 1998).

The IEUBK model contains more than 100 input parameters that are initially set to default values. These default values are generally intended to represent national averages or other central tendency values to be used in the absence of site-specific exposure data. Default values are derived from a) empirical data in the open literature that included lead concentrations in exposure media (e.g., concentration of lead in drinking water), b) contact rates such as the soil/dust ingestion, and c) exposure durations (White et al., 1998). In general, information used to support a risk assessment can be characterized as either site-specific environmental media data or community-specific socioeconomic and receptor data. While environmental media data (*e.g.*, air, water, soil) are the most common type of site-specific data entered into the IEUBK model, default values for socioeconomic and receptor data, such as age, body weight, breathing rate or soil ingestion rate, do not typically vary from site to site and are rarely adjusted in the IEUBK model.

The current default value for the *Lead Concentration in Drinking Water* variable in the IEUBK model represents a national central tendency estimate for lead concentration in drinking water (PbW). This value was derived from a combination of PbW data reported by the American Water Works Service Company, Inc. (AWWSC, 1988) and a quantitative analysis performed by Marcus (1989).[3] The TRW recommends updating the *Lead Concentration in Drinking Water* variable with a value derived from the U.S. EPA's Second Six-Year Review of National Primary Drinking Water Regulations, or "Six-Year Review" (US EPA, 2010a,b; see Table 1).[4]

The purpose of this document is to review the currently available data on lead in U.S. drinking water, provide the technical basis for updating the *Lead Concentration in Drinking Water* variable, and to

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[1]The GM represents the central tendency estimate (*e.g.*, mean, 50[th] percentile) of PbB concentration of children from a hypothetical population (Hogan et al., 1998). It is recognized, however, that a central tendency estimate is equally likely to over- or under-estimate the lead-intake at a contaminated site. Upper confidence limits (UCLs) can be used in the IEUBK model; however, the IEUBK model results could be interpreted as a more conservative estimate of the risk for an elevated blood lead level. See U.S. EPA (1994b) for further information.

[2]The IEUBK model uses a log-normal probability distribution to characterize this variability (U.S. EPA, 1994a). The biokinetic component of the IEUBK model output provides a central estimate of blood lead concentration In the IEUBK model, the GSD is intended to reflect only individual blood lead variability, not variability in blood lead concentrations where different individuals are exposed to substantially different media concentrations of lead. The recommended default value for GSD (1.6) was derived from empirical studies with young children where both blood and environmental lead concentrations were measured (White et al., 1998).

[3] The AWWSC (1988) performed a survey of the trace element concentrations and characteristics of 1,484 locations throughout the United States (U.S. EPA, 1994a,b).

[4] Due to ongoing analyses of lead in drinking water, the lead dataset was not published as part of the Six-Year Review of National Primary Drinking Water Regulations (U.S. EPA, 2010a). The lead concentration in drinking water dataset obtained from the 1998-2005 National Compliance Monitoring Information Collection Request Dataset (*i.e.*, "Six-Year Review-ICR Dataset"), however, was delivered by U.S. EPA Office of Groundwater and Drinking Water to the TRW for this review. For more information see http://water.epa.gov/scitech/datait/databases/drink/sdwisfed/howtoaccessdata.cfm.

recommend an updated default PbW value for use in the IEUBK model. The intended audience for this document is risk assessors who are familiar with using the IEUBK model. For further background information on the use of the IEUBK model in Superfund lead risk assessment, refer to U.S. EPA (1994a) or the Technical Review Workgroup for Lead (TRW) website (http://epa.gov/superfund/lead/trw.htm).

Table 1. Comparison of water lead concentrations for use in the IEUBK model.

Source	Constant Water Lead Concentration (µg/L)	Basis for Age-Specific Value
IEUBK Model Default[a]	4	<u>Methodology</u> Marcus, 1989 Central tendency estimate <u>Water Lead Concentration Data</u> American Water Works Service Company, Inc. (AWWSC, 1988)
Proposed Drinking Water Lead Concentration Value[b]	[redacted]	<u>Methodology</u> Population-weighted, estimate of high end exposure data <u>Water Lead Concentration Data</u> 1998-2005 Six-Year Review-ICR Dataset (U.S. EPA, 2010a)

[a] IEUBK model v. 1.1, build 11.
[b] Value is intended to be a nationally representative, population-weighted, estimate of high end water lead concentration found in tap water in the U.S. This value does not represent filtered or bottled water consumption. Order of operations: Calculated mean population per sample: 22,022 observations; all samples multiplied by population weight factor: value * (population / mean population); mean of all samples by location; mean of all means by location.

Technical Analysis

The TRW identified information on PbW from seven sources (Clayton et al. 1999; Moir et al., 1996; U.S. EPA, 2006a, 2007, 2008, 2010a,c). See Table 2 for an overview of these sources. U.S. EPA (2008, 2010c) and the National Ambient Air Quality Standards (NAAQS) analysis (U.S. EPA, 2006a, 2007) suggest that a constant mean water lead concentration of 4.61 µg/L is appropriate based on data from two studies of residential water concentrations in U.S. and Canadian homes (Clayton et al., 1999, Moir et al., 1996).

Clayton et al. (1999) based PbW estimates on the results of the National Human Exposure Assessment Survey (NHEXAS) Phase I field studies conducted by the Research Triangle Institute and the Environmental and Occupational Health Sciences Institute. Phase I was conducted in six states in U.S. EPA Region 5 (Ohio, Michigan, Illinois, Indiana, Wisconsin, and Minnesota) between July 1995 and May 1997. The study included a series of questionnaires of personal exposure and onsite physical samples of residential water (both first-draw and flushed).[5] Clayton et al. (1999) reported the arithmetic mean drinking water concentration for the Region 5 areas as follows: first-draw (n=444) water 3.92 µg/L (95% CI: 3.1 to 4.8) and flushed water (n=443) 0.84 µg/L (95% CI: 0.6 to 1.1) (see Table 2).

[5] The NHEXAS study was a federal interagency research effort coordinated by the U.S. EPA Office of Research and Development (ORD). NHEXAS was implemented in three phases: Phase I, scoping studies using probability-based sampling designs; Phase II, a full national exposure survey; and Phase III, a series of focused characterization modules (Pellizzari et al. 1995). Pellizzari et al. (1995) and Clayton et al. (1999) provide further detail the scope and design of Phase I of the NHEXAS study.

Moir et al. (1996) summarized data on PbW from 36 single-family homes serviced by municipal water drawn from a lake in Halifax, Nova Scotia, Canada. Two tap water samples over two separate occasions were collected from each location in April and June, 1987. Moir et al. (1996) noted that many of the homes sampled were serviced by lead pipe mains, and that 70% and 25% of the first-draw and flushed water samples, respectively, from the homes sampled had lead concentrations that exceeded 10 µg/L. The mean lead concentration for first-draw water was 16 µg/L (maximum=51 µg/L), and for flushed water was 8 µg/L (maximum=70 µg/L) (see Table 2).

Table 2. Comparison of constant lead concentration in drinking water values.

Source	Constant Water Lead Concentration (µg/L)	Basis for Value	
IEUBK Model Default[a]	4	Marcus, 1989	American Water Works Service Company, Inc. (AWWSC, 1988)
Proposed Value[b]	[redacted]	U.S. EPA, 2010a Population-weighted, mean estimate of high end exposure data	1998-2005 Six-Year Review-ICR Dataset
Current Analysis	[redacted]	Geometric mean	1998-2005 Six-Year Review-ICR Dataset
	[redacted]	Population-weighted, mean estimate of high end exposure data	1998-2005 Six-Year Review-ICR Dataset
U.S. EPA, 2010b	4.61	U.S. EPA, 2008 U.S. EPA, 2007 U.S. EPA, 2006a Clayton et al., 1999 Moir et al., 1996 Geometric mean	1995-1997 NHEXAS Phase I Field Study, U.S. EPA Region 5[c] 1987 Sampling efforts in Halifax, Nova Scotia, Canada[d]
Clayton et al., 1999	3.92	Mean first-draw tap water	1995-1997 NHEXAS Phase I Field Study, U.S. EPA Region 5[c]
	0.84	Mean flushed tap water	
Moir et al., 1996	16	Mean first-draw tap water	1987 Sampling Efforts in Halifax, Nova Scotia, Canada[d]
	8	Mean flushed tap water	

[a] IEUBK model v. 1.1, build 11.
[b] Value represents the population-weighted mean estimate of high end exposure data rounded to one significant figure. Value is intended to be a nationally representative water lead concentration found in tap water in the U.S. This value does not represent filtered or bottled water consumption.
[c] Values represent 444 and 443 samples for first-draw and flushed tap water, respectively. Data were collected in U.S. EPA Region 5 from the six states (Illinois, Indiana, Ohio, Michigan, Minnesota, and Wisconsin) between July 1995-May 1997.
[d] Values represent 36 samples collected from single-family homes in the city of Halifax, Nova Scotia, Canada between April and June 1987.

Amendments to the Safe Drinking Water Act require U.S. EPA to review each National Primary Drinking Water Regulations (NPDWR) every six years. This process, or "Six-Year Review", is a comprehensive assessment of drinking water quality that measures the state of water treatment capabilities, as well as current laboratory analytical methods for the regulated contaminants (U.S. EPA, 2010b).[6] As described by U.S. EPA (2010d), during the Six-Year Review process, public water systems must sample homes or other sites with plumbing materials expected to contain lead or copper (*i.e.*, homes connected to water mains by lead pipes, etc.) to detect elevated levels of chemicals (*e.g.*, lead). In addition, drinking water samples must be first draw following a 6-hour stagnation period to allow for corrosion effects to accumulate. The findings of the sampling efforts are reported to the respective Primacy Agency (*i.e.*, states and tribes with primary enforcement authority under the Safe Drinking Water Act) in accordance with 40 CFR 141.90 of the Lead and Copper rule, and additional actions are taken if elevated levels of lead are present (U.S. EPA, 2010d).

Data obtained from the 1998-2005 Six-Year Review-ICR Dataset (U.S. EPA, 2010a) consisted of 45 States and Primacy Agencies that comprised of 44,257 individual sample monitoring records.[7] On average, 883 water suppliers contributed data from each state; the number of suppliers varied from one in Tennessee to 5,557 in Texas; on average, 883 water suppliers voluntarily contributed data. The calculated geometric mean PbW was [redacted] µg/L (95% CI= [redacted] to [redacted] µg/L; see Table 3). In addition, a population-weighted mean PbW of [redacted] µg/L (95% CI= [redacted] to [redacted] µg/L) was calculated based on the population served by each water supplier (see Table 4). The frequency distribution of lead concentration reported by water suppliers is presented in Figures 1 and 2. Estimates for lead concentration were calculated using Microsoft Access. Calculated mean population per sample: 22,022 observations. The order of operations was as follows: all samples multiplied by population weight factor: *value * (population / mean population)*, then the mean of all samples by location and finally the mean of all means by location.

Table 3. Summary statistics for mean water lead concentration (µg/L) based on data reported by the U.S. EPA Office of Groundwater and Drinking Water 1998-2005 Six-Year Review-ICR Dataset (U.S. EPA, 2010a)[a]

Mean	GSD	Min	Max	N	SEM
[redacted]	54.4	1×10^{-5}	56.3×10^{3}	44257	0.26

Confidence Limit	T	MinCL (µg/L)	MaxCL (µg/L)
50%	0.674	4.71	5.06
60%	0.842	4.67	5.1
70%	1.036	4.62	5.15
80%	1.282	4.55	5.22
90%	1.645	4.46	5.31
95%	1.960	4.38	5.39
98%	2.326	4.28	5.49
99%	2.576	4.22	5.55

Mean: geometric mean water lead concentration; StDev: standard deviation; Min: minimum water lead concentration; Max: maximum water lead concentration, N: number of samples; SEM: standard error of the mean; T: t statistic; MinCL: minimum confidence limit; MaxCL: maximum confidence limit

[a]See U.S. EPA (2010a) for detailed information such as analytical sensitivity, laboratory QA/QC methods, etc.

[6]A national database for receiving and storing public water system data has not been established, and the Six-Year Reviews rely on voluntary reporting of data from the states, territories and tribes (U.S. EPA, 2010b).

[7]The monitoring records were voluntarily obtained from 45 States and Primacy Agencies (including two Tribal Nations located in U.S. EPA Region 8 and Region 9), and represented approximately 250 million people nationally. The database did not include data from Kansas, Louisiana, Maryland, Mississippi, New Hampshire, Pennsylvania, and Washington state.

Table 4. Summary statistics for population-weighted mean water lead concentration (µg/L) based on data reported by the U.S. EPA Office of Groundwater and Drinking Water 1998-2005 Six-Year Review-ICR Dataset (U.S. EPA, 2010a)

Mean[a]	StDev	Min	Max	N	S.E.M.
[redacted]	12.4	7.95×10^{-8}	1.56×10^{3}	44257	5.9×10^{-2}

Confidence Limit	T	MinCL (µg/L)	MaxCL (µg/L)
50%	0.674	0.85	0.93
60%	0.842	0.84	0.94
70%	1.036	0.83	0.95
80%	1.282	0.82	0.97
90%	1.645	0.79	0.99
95%	1.960	0.78	1.01
98%	2.326	0.75	1.03
99%	2.576	0.74	1.04

Mean: population-weighted mean lead concentration; StDev: standard deviation; Min: minimum water lead concentration; Max: maximum water lead concentration, N: number of samples; SEM: standard error of the mean; T: t statistic; MinCL: minimum confidence limit; MaxCL: maximum confidence limit

[a]Order of operations: Calculated mean population per sample: 22,022 observations; all samples multiplied by population weight factor: value * (population / mean population); mean of all samples by location; mean of all means by location.

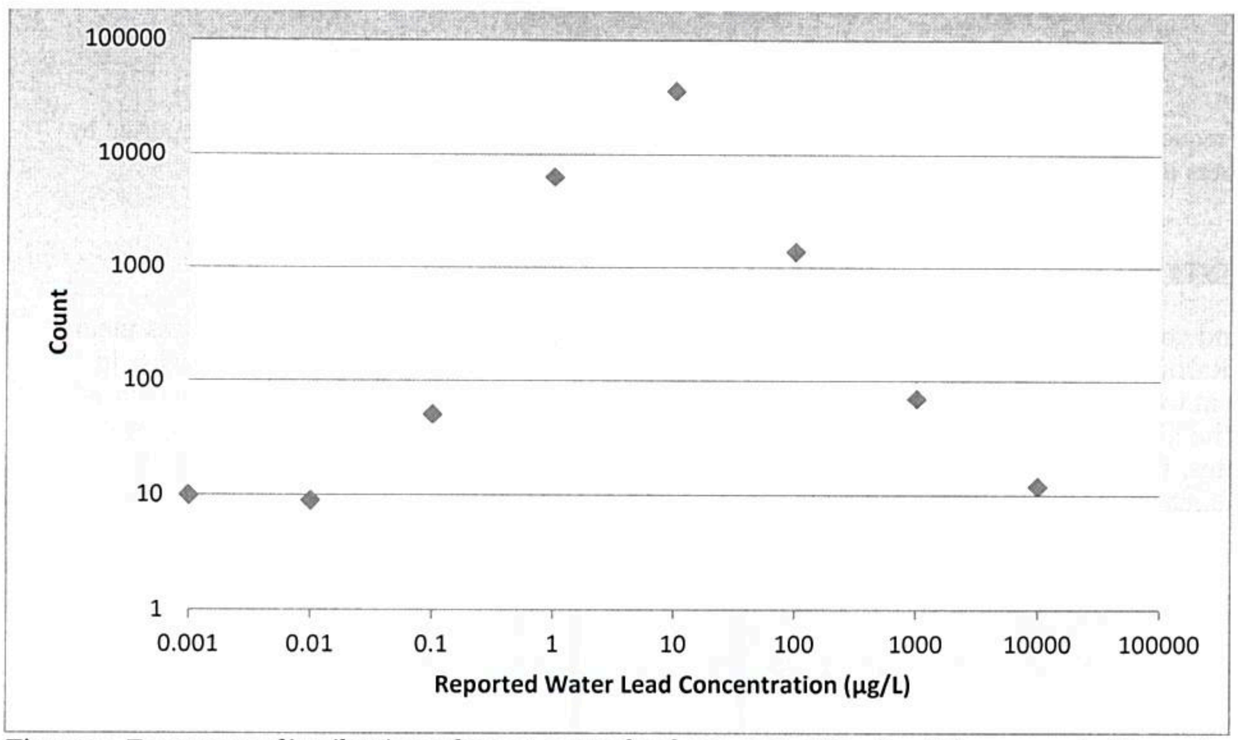

Figure 1. Frequency distribution of mean water lead concentration (µg/L) as reported by water suppliers in the 1998-2005 Six-Year Review-ICR Dataset (U.S. EPA, 2010a).

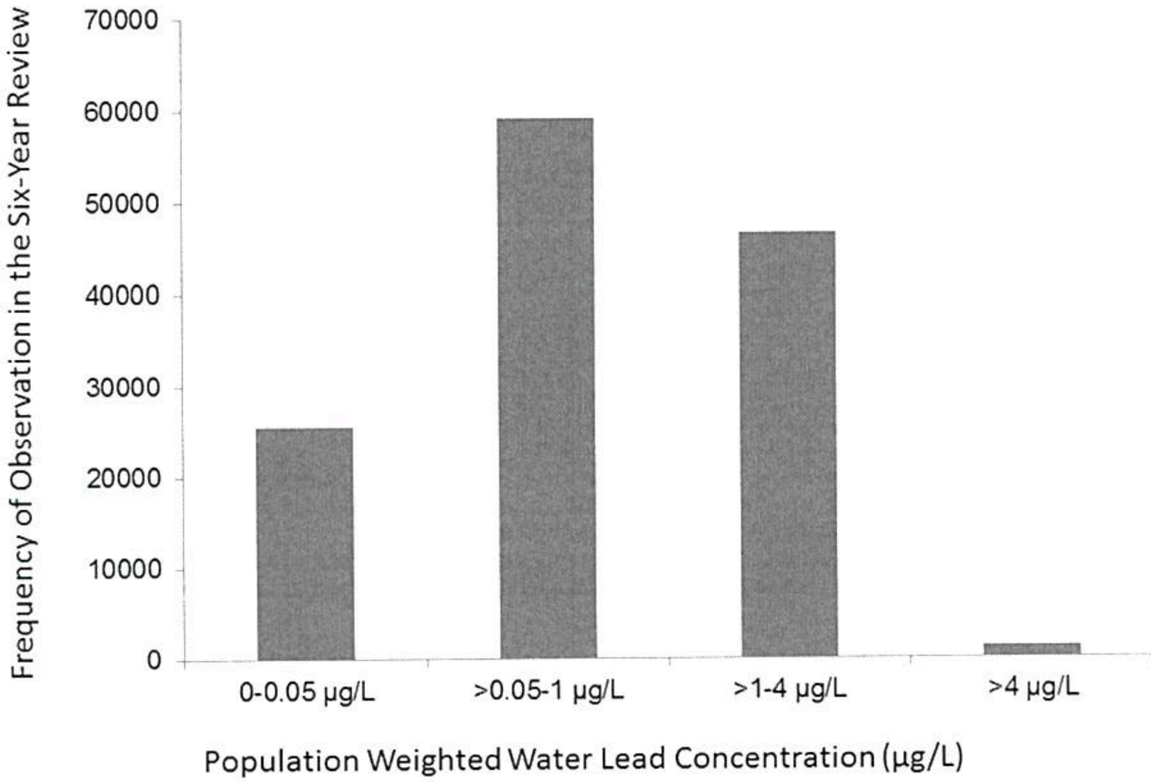

Figure 2. Frequency distribution for the population-weighted water lead concentrations (µg/L) as reported by water suppliers in the 1998-2005 Six-Year Review-ICR Dataset (U.S. EPA, 2010a).

UNCERTAINTY

The lead and copper sampling requirements in the Six-Year Review are not designed to assess mean exposure. Rather, the sampling is intended to detect elevated levels of lead if they are occurring in a water system in order to trigger additional actions to reduce lead and copper exposure. These data likely represent the higher levels of lead found in homes served by public water systems throughout the United States. Further, EPA did not conduct quality assurance activities on the data to identify anomalies such as incorrect units, duplicate samples, etc.

RECOMMENDATIONS FOR THE IEUBK MODEL

As described in U.S. EPA (2006a, 2007, 2008, 2010a,c), the range of values (0.84 to 16 µg/L) observed in Clayton et al. (1999) and Moir et al. (1996) was considered to be representative of randomly sampled residential water in houses constructed since lead pipe and solder were banned for residential use. The mean water concentration of [redacted] µg/L value, however, does not address elevated background exposures encountered in homes with Pb piping and/or very corrosive water.[8]

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[8] If the Clayton et al. (1999) values are entered in the IEUBK model alternate water menu (in place of current and proposed defaults: 4 µg/L and [redacted]L, respectively), the calculated water lead concentration is [redacted]µg/L. The current default value (4 µg/L) would be within the confidence limits on the latter estimate (3.31 to 4.19 µg/L). Thus, the Clayton et al. (1999) study does not provide strong support for changing the current default value of 4 µg/L. The data reported in Moir et al. (1996) does not represent a statistically robust sample of the lead concentrations in U.S. drinking water, for the following reasons: (1) the relatively small sample size (n=36); (2) limited geographic area of the sample (one area of Nova Scotia); and (3) the potential contribution of lead from lead pipe mains to the water in the sample.

The Six-Year Review is considered as the "largest and most comprehensive contaminant occurrence dataset ever compiled and analyzed by EPA's Drinking Water Program" (U.S. EPA, 2010b). As such, the TRW considers this dataset as an appropriate source of information to serve as the basis for updating the IEUBK model. Based on the analysis outlined in this document, the TRW recommends updating the default *Lead Concentration in Drinking Water* variable in the IEUBK model using the population-weighted mean estimate derived from the 1998-2005 Six-Year Review-ICR Dataset (U.S. EPA, 2010a). This default value is considered appropriate for all applications of the IEUBK model where current and future residential scenarios are being assessed. The TRW recommends replacing the default with site-specific information if representative site-specific information is available that meet the Data Quality Objectives of the site.[9] Site-specific data may include water lead concentration sampling or using local water compliance monitoring data which reports 90th percentile values. The site-specific information can be evaluated against the default the IEUBK model value to derive an appropriate input for risk assessment. Although site-specific measures will best represent drinking water, there is also a need to run exposure scenarios in the absence of site-specific data (i.e., a default value is necessary). The Superfund Lead-Contaminated Residential Sites Handbook has further information on collecting site-specific water lead concentration data (U.S. EPA, 2003).

IMPACT ON THE IEUBK MODEL PREDICTIONS

Based on using current IEUBK model (v. 1.1, build 11) defaults for all other parameters, implementing the proposed water lead concentration will decrease the geometric mean blood lead concentration for children (0-84 months of age) from 2.730 to 2.493 µg/dL (Table 5). Significant impacts on the predicted blood Pb for any age group, on the probability of the geometric mean exceeding 10 µg/dL, and on PRGs in the soil lead concentration range in the interest for OSRTI were not observed (Table 5).

The proposed value is based on national water concentration averages; however, this value may not necessarily represent subpopulations of children at sites. The IEUBK model will continue to allow (as shown in Figure 3) for input of site-specific water concentration information (*e.g.*, first-draw, flushed, water fountains) that meet the Data Quality Objectives of the site.

[9] To promote defensible and reproducible site investigations and decision making, while maintaining flexibility needed to respond to different site conditions, U.S. EPA recommends the Data Quality Objectives process (U.S. EPA, 2006b). Data Quality Objectives provide a structured approach to collecting environmental data that will be sufficient to support decision-making.

Table 5. Comparison of the IEUBK model output for selected lead concentrations in drinking water.

Parameter	Age Range (months)								GM	P_{10}	PRG for 5% NTE	
	0 < 12	12 < 24	24 < 36	36 < 48	48 < 60	60 < 72	72 < 84	12 -71[c]			5 µg/dL (ppm)	10 µg/dL (ppm)
IEUBK Model Default Value (4 µg/L)[a]												
Lead uptake from water (µg/day)	0.375	0.929	0.976	1.004	1.059	1.123	1.146	0.91	2.730	0.287	153	418
Calculated Total Lead Uptake (µg/day)	5.586	8.368	8.593	8.651	7.045	6.720	6.592	7.5				
Calculated Geometric Mean Blood Lead Concentration (µg/dL)	3.0	3.5	3.2	3.0	2.5	2.1	1.9	2.8				
Proposed IEUBK model default Value ([redacted] µg/L)[b]												
Lead uptake from water (µg/day)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Calculated Total Lead Uptake (µg/day)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]				
Calculated Geometric Mean Blood Lead Concentration (µg/dL)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]				

GM: Geometric mean blood lead concentration (µg/dL) for 0-84 month age range; P10: Probability of the predicted GM blood lead concentration ≤ 10 µg/dL; PRG: preliminary remediation goal; NTE: not to exceed

[a] IEUBK Model (v. 1.1, build 11)

[b] Value based on the analysis of the 1998-2005 Six-Year Review-ICR Dataset (U.S. EPA, 2010a) performed for this review.

[c] To better align the CDC recommendation and the risk predictions for lead exposure at Superfund sites, the TRW Lead Committee recommends that the default age range in EPA's tool for determining risk from lead exposure (the Integrated Exposure Uptake Biokinetic Model for Lead in Children; IEUBK model) be modified to match the 1-5 year age range (12-71 months). The values shown are approximate for the 12-71 month age range.

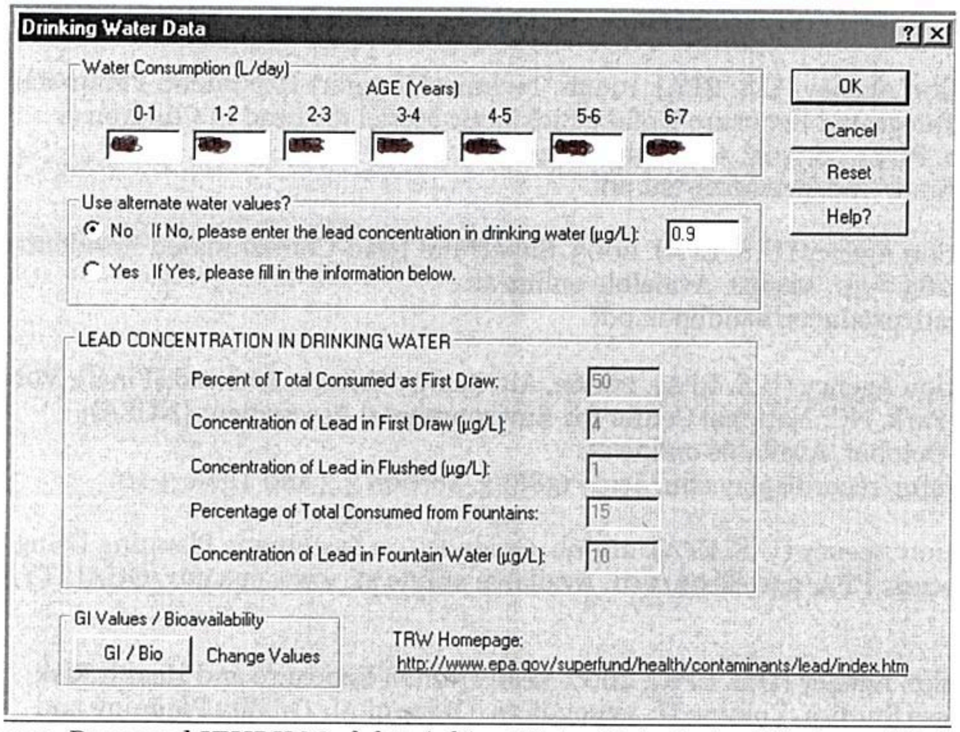

Figure 3. Proposed IEUBK Model Drinking Water Data Entry Window with the Recommended Drinking Water Lead Concentration Value.

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ESTIMATION OF DAILY WATER CONSUMPTION FOR U.S. CHILDREN

OVERVIEW

Since 1994, the Office of Solid Waste and Emergency Response (OSWER) has recommended the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK model) as a risk assessment tool to support environmental cleanup decisions at residential sites (U.S. EPA, 1994a, b). The IEUBK model uses empirical data from numerous scientific studies of lead uptake and biokinetics, contact rates of children with contaminated media, and data on the presence and behavior of environmental lead to predict a plausible distribution or geometric mean (GM) of blood lead (PbB) for a hypothetical child or population of children.[1] The relative variability of PbB concentrations around the GM is defined as the geometric standard deviation (GSD). The GSD encompasses biological and behavioral differences, measurement variability from repeat sampling, variability as a result of sample locations, and analytical variability.[2] From this distribution, the IEUBK model estimates the risk (*i.e.*, probability) that a child's or a population of children's PbB concentration will exceed a certain level of concern (recorded as "$P_{\text{level of concern}}$") (U.S. EPA, 1998, 1994a; White et al., 1998).[3]

The default background values for the *Water Consumption* variable in the IEUBK model represent age-specific central tendency estimates for lead intake from water in the absence of exposures at the site being assessed. These default consumption rates were derived from the water (and water-based foods) consumption values from the U.S. Department of Agriculture's 1977-78 Nationwide Food Consumption Survey (NFCS; USDA, 1984) and the Department of Health and Human Services 1976-80 National Health and Nutrition Examination Survey (NHANES; U.S. DHHS, 1983) as reported in the Exposure Factors Handbook (U.S. EPA, 1989). Of the approximately 6,300 foods obtained from the NFCS and NHANES surveys, a representative list of commonly consumed water-based foods (water, coffee, tea, reconstituted juices, and reconstituted soups) was paired with the daily water intake information from the NFCS and used to predict total water consumption in the United States (U.S. EPA, 1989; Pennington, 1983).

[1]The GM represents the central tendency estimate (*e.g.*, mean, 50th percentile) of PbB concentration of children from a hypothetical population (Hogan et al., 1998). If an arithmetic mean (or average) dietary intake is used, the model provides a central point estimate for risk of an elevated PbB level. By definition, a central tendency estimate is equally likely to over- or under-estimate the lead-intake at a contaminated site. Upper confidence limits (UCLs) can be used in the IEUBK model; however, the IEUBK model results could be interpreted as a more conservative estimate of the risk of an elevated PbB level. See U.S. EPA (1994b) for further information.

[2]The IEUBK model uses a log-normal probability distribution to characterize this variability (U.S. EPA, 1994a). The biokinetic component of the IEUBK model output provides a central estimate of PbB level, which is used to provide the geometric standard deviation (GSD). The GSD encompasses biological and behavioral differences, measurement variability from repeat sampling, variability as a result of sample locations, and analytical variability. In the IEUBK model, the GSD is intended to reflect only individual PbB variability, not variability in PbB levels where different individuals are exposed to substantially different media concentrations of lead. The recommended default value for GSD (1.6) was derived from empirical studies with young children where both blood and environmental lead concentrations were measured (White et al., 1998).

[3]For example, using current IEUBK model default exposure values, the probability of children with a PbB above 10 µg/dL is 0.287%. This value would be recorded as "P_{10}=0.287%".

The purpose of this document is to provide a recommendation for revising the *Water Consumption* variable in the IEUBK model using a more representative methodology for estimating water consumption, and a more recent daily average water consumption rates. The recommended estimates for the *Water Consumption* variable in the IEUBK model are based on the 1994-1996 and 1998 Continuing Survey of Food Intakes by Individuals (CSFII; USDA, 2000) as reported by Kahn and Stralka (2009). Linear interpolation was used to estimate water consumption rates for the IEUBK model age groups, from consumption rates reported by Kahn and Stralka (2009) (Table 1).

Table 1. Comparison of age-specific water consumption rates for use in the IEUBK model.

Source	**Age Category (months)**							**Basis for Age-Specific Value**
	0<12	**12<24**	**24<36**	**36<48**	**48<60**	**60<72**	**72<84**	
IEUBK Model Default[a]	0.2	0.5	0.52	0.53	0.55	0.58	0.59	<u>Methodology</u> U.S. EPA, 1989 U.S. EPA, 1984 Pennington, 1983 <u>Data Source</u> 1976-1980 NHANES (U.S. DHHS, 1983) 1977-1978 NFCS (USDA, 1984)
Proposed Water Consumption Rates[b]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	<u>Methodology</u> Kahn and Stralka, 2009 (All Water Sources, Consumers Only) <u>Data Source</u> 1994-1996 & 1998 CSFII (USDA, 2000)

[a]IEUBK model v. 1.1, build 11.
[b]Linear interpolations of the known Kahn and Stralka (2009) data points were performed in Microsoft Office Excel 2007®.

This document provides the technical basis for updating the *Water Consumption* variable in the IEUBK model. The intended audience for this document is risk assessors who are familiar with using the IEUBK model. For further background information on the use of the IEUBK model in Superfund lead risk assessment, refer to U.S. EPA (1994a) or the Technical Review Workgroup for Lead (TRW) website (http://epa.gov/superfund/lead/trw.htm).

<u>INTRODUCTION</u>

The IEUBK model predicts PbB in young children exposed to lead from several sources and routes. The IEUBK model uses more than 100 input parameters that are initially set to default values. Of these, there are 46 parameters that may be input, or modified, by the user; the remainder are locked (U.S. EPA, 1994a). Default values represent national averages or other central tendency values derived from: a) empirical data in the open literature that included lead concentrations in exposure media (*e.g.*, diet representative of national food sources), b) contact rates, such as the soil/dust ingestion, and c) exposure durations (White et al., 1998). The representativeness of IEUBK model output is wholly dependent on the representativeness of the data (often assessed in terms of completeness, comparability, precision, and accuracy [U.S. EPA, 1994a]).

Site-specific data are essential for risk assessment support for developing cleanup goals. Because there may be potentially important differences among sites, using representative site- and community-specific information that reflects exposure conditions at the site will improve the accuracy of the IEUBK model predictions. The most common type of site-specific data is exposure point concentrations for air, water, soil, and dust. Such data are typically collected as part of the site characterization. Receptor information related to exposure to lead in local water sources (concentration and consumption rates) may be collected on a site-specific basis for use in the alternate diet module of the IEUBK model; however, changes to the default water consumption values would generally not be appropriate based on site-specific information.

To promote defensible and reproducible site investigations and decision making, while maintaining flexibility needed to respond to different site conditions, EPA recommends the Data Quality Objectives process (U.S. EPA, 2006). Data Quality Objectives provide a structured approach to collecting environmental data that will be sufficient to support decision-making: http://www.epa.gov/QUALITY/dqos.html.

The CFSII was a nationwide food survey that was conducted by the U.S. Department of Agriculture's Agricultural Research Service (from 1985-1998). The CSFII was designed to collect a representative sample of the type and amount of foods consumed in the U.S. The 1994-1996 and 1998 surveys consisted of two, in-home, 24-hour dietary recall interviews that recorded all foods and water consumed during the day preceding the interview. The interviews were implemented at least three days apart to reduce dependence between the two recalls (USDA, 2000). Self-reported body weights were also provided which support population and subpopulation (*e.g.*, age-specific groups) estimates of water consumption rates (U.S. EPA, 2009). Data from the 1989-1991 CSFII were analyzed and ultimately not recommended for use in the Exposure Factors Handbook (U.S. EPA, 1997); however, U.S. EPA (2011, 2009, 2008, 2007, 2004) and Kahn and Stralka (2009) provided childhood estimates based on the 1994-1996 and 1998 CSFII (USDA, 2000).

Kahn and Stralka (2009) and U.S. EPA (2004) provide an analysis of the strengths of using the 1994-1996 and 1998 CSFII data to estimate water consumption. Briefly, the principal advantages of this survey are:

(1) the survey was designed to obtain a representative sample of the non-institutionalized United States population that over-sampling children and low income groups;
(2) sample weights were provided that facilitated proper analysis of the data and accounted for non-response; and
(3) the number of individuals sampled (more than 20,000) is sufficient to allow categorization within narrowly defined age categories. The sample size for children younger than 11 years of age (from 4,339 in the initial 1994-96 survey to 9,643 children in the combined 1994-96 and 1998 surveys) enabled water consumption estimates to be categorized into the finer age categories recommended by U.S. EPA (2005)[4]. The over-sampling of children enhanced the precision and accuracy of the estimates for the child population subsets.

The NHANES is a continuous survey that is designed to assess the health and nutritional status of children and adults in the U.S. (http://www.cdc.gov/nchs/nhanes.htm). U.S. CDC releases

[4]Age Ranges recommended by U.S. EPA, 2005: <1 month, 1 to <3 months, 3 to <6 months, 6 to <12 months, 1 to <2 years of age, 2 to <3 years, 3 to <6 years, 6 to <11 years, 11 to <16 years, 16 to <18 years, and 18 to <21 years of age, 21 years and older, 65 years and older, and all ages.

data from the NHANES in 2-year increments as one dataset, and recommends using four or more years of data (*i.e.*, two or more datasets) when estimating parameters for demographic sub-domains (U.S. CDC, 2006).

The dietary component of the NHANES survey [*i.e.*, What We Eat in America (WWEIA)] is conducted as a partnership between USDA and the U.S. DHHS. The WWEIA includes two 24-hour dietary recall interviews to query all foods and portion sizes consumed during the prior 24 hours. Although the recall is limited to foods consumed for a single day, it provides very detailed and reliable data (*e.g.*, brand names for bottled water, time the water was consumed and some information on water sources).[5] The second most commonly used dietary survey instrument is the food frequency questionnaire (FFQ), which typically collects information about food consumption over a much longer period of time (*e.g.*, the year preceding the date of the interview). However, the FFQ typically collects only data on consumption frequency; information about the quantity of food consumption, which is required to estimate dietary intake rates, is not collected.

TECHNICAL ANALYSIS

The TRW identified information on age-specific childhood water consumption rates from six sources (U.S. EPA, 2011, 2007, 2004; Kahn and Stralka, 2009; WHO, 2005; see Table 2). Linear interpolation was used with data provided from each of these studies to estimate age-specific consumption rates for use in the IEUBK model (Table 3).[6] Age-specific water consumption rates were calculated using the following general equation:

$$y = [y_1 + (x - x_1)] * [(y_2 - y_1) / (x_2 - x_1)]$$

Where:
y = water consumption rate
x = age

An impact analysis of the recommended data was performed using the IEUBK model (v. 1.1, build 11).

Information on dietary intakes, including water consumption, was extracted from the NHANES WWEIA data files (U.S. CDC, 2010a,b). Data from the two most recent 2-year cycles (2003-04 & 2005-06)[7] were used, in accordance with U.S. CDC recommendations (U.S. CDC, 2006). A comparison of the sample sizes available from the 2003-04 and 2005-06 WWEIA and the 1994-96 & 1998 CSFII survey data are provided in Table 4.

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[5] The types of information available for water consumption varies between NHANES survey years.

[6] Linear interpolation is a method that has been used by U.S. EPA (2010, 2007) to estimate an unknown value that lies between two data points. Further information on calculating linear interpolation with Microsoft Excel is available online at: http://www.blueleafsoftware.com/Products/Dagra/LinearInterpolationExcel.php#HowItWorks

[7] The 2003-04 & 2005-06 dietary data were the most recent available data at the time this research was initiated.

Table 2. Comparison of age-specific water consumption rates

Source	Age Range (months)	Constant Water Consumption (L/day)	Basis for Age-Specific Value	
IEUBK Default[a]	0 < 12 12 < 24 24 < 36 36 < 48 48 < 60 60 < 72 72 < 84	0.20 0.50 0.52 0.53 0.55 0.58 0.59	U.S. EPA, 1989 U.S. EPA, 1984 Pennington, 1983	Data Source 1977-1978 NFCS (USDA, 1984) 1976-1980 NHANES (U.S. DHHS, 1983)
Kahn and Stralka, 2009[b]	0 < 1 1 < 3 3 < 6 6 < 12 12 < 24 24 < 36 36 < 72 72 < 132	0.511 0.555 0.629 0.567 0.366 0.439 0.518 0.603	All Water Sources, Consumers Only	Data Source 1994-1996, 1998 CSFII (USDA, 2000)
U.S. EPA, 2011	0 < 1 1 < 3 3 < 6 6 < 12 12 < 24 24 < 36 36 < 72 72 < 132	0.470 0552 0.556 0.467 0.308 0.356 0.417 0.480	Kahn and Stralka, 2009 U.S. EPA, 2009 U.S. EPA, 2008 (Community Water Sources, Consumers Only)	Data Source 1994-1996, 1998 CSFII (USDA, 2000)
	0 < 1 1 < 3 3 < 6 6 < 12 12 < 24 24 < 36 36 < 72 72 < 132	0.184 0.227 0.362 0.360 0.271 0.317 0.380 0.447	Kahn and Stralka 2009 U.S. EPA, 2009 U.S. EPA, 2008 (Community Water Sources, All Individuals)	Data Source 1994-1996, 1998 CSFII (USDA, 2000)
U.S. EPA, 2007	6 < 12 12 < 24 24 < 36 36 < 48 48 < 60 60 < 72 72 < 84	0.34 0.31 0.31 0.33 0.36 0.39 0.42	U.S. EPA, 2002 U.S. EPA, 2000 (Community Water Sources, All Individuals)	Data Source 1994-1996, 1998 CSFII (USDA, 2000)
WHO, 2005	0 < 6 7 < 12 12 < 36 36 < 96	0.7 0.8 1.3 1.7	IOM, 2005	Data Source IOM, 2005
U.S. EPA, 2004	0 < 5 6 < 11 12 < 36 48 < 72 72 < 156	0.296 0.360 0.311 0.406 0.453	U.S. EPA, 2002 U.S. EPA, 2000 (Community Water Sources, All Individuals)	Data Source 1994-1996, 1998 CSFII (USDA, 2000)
U.S. EPA, 1997	0 < 12 0 < 36 36 < 60 12 < 120	0.302 0.61 0.87 0.736	Roseberry and Burmaster, 1992 Ershow and Cantor, 1989 CMNHW, 1981	Data Source 1977-1978 NFCS (USDA, 1984) CMNHW, 1981

[a] IEUBK model (v. 1.1, build 11)
[b] Values were the basis of the proposed IEUBK model updates.

Table 3. Water consumption rates for impact analysis.

Source	Age (months)						
	0 < 12	**12 < 24**	**24 < 36**	**36 < 48**	**48 < 60**	**60 < 72**	**72 < 84**
IEUBK Default[a]	0.2	0.5	0.52	0.53	0.55	0.58	0.59
Proposed Water Consumption Rates[b]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
U.S. EPA, 2011[c]	0.33	0.35	0.41	0.44	0.46	0.48	0.50
U.S. EPA, 2011[d]	0.29	0.31	0.37	0.40	0.42	0.45	0.47
U.S. EPA, 2007	0.34	0.31	0.31	0.33	0.36	0.39	0.42
WHO, 2005	0.78	1.21	1.66	1.70	1.70	1.70	1.70
U.S. EPA, 2004	0.36	0.34	0.31	0.34	0.37	0.40	0.42

[a] IEUBK Model (v. 1.1, build 11)
[b] Kahn and Stralka, 2009; all water sources, consumers only
[c] Kahn and Stralka, 2009; community water sources, consumers only
[d] Kahn and Stralka, 2009; community water sources, all individuals

Table 4. Sample size comparison (number of participants) by age range for the CSFII as compared to NHANES (WWEIA) 2003-2004 and 2005-2006. The number of survey participants is shown in parentheses.

CSFII 1994-96 & 1998[a]	**NHANES (WWEIA) 2003-2006 (IEUBK Age groups)[b]**
< 1 (58)	0 < 12 months (820)
1 < 3 (178)	
3 < 6 (363)	
6 < 12 (667)	
12 < 24 (1017)	12 < 24 months (559)
24 < 36 (1051)	24 < 36 months (510)
36 < 72 (4350)	36 < 48 months (308)
	48 < 60 months (363)
	60 < 72 months (304)
72 < 132 (1659)	72 < 84 months (331)
	≥84 months (13,299)

[a] Source: Kahn and Stralka, 2009; Table 1. Consumers only, Total Water.
[b] Sample sizes correspond to individuals with two days of complete and reliable dietary recall data (CDC, 2010a, b).

UNCERTAINTY

Estimating long-term average daily consumption rates from short-term 24-hour dietary recalls requires an assumption that the 24-hour recalls provide an unbiased estimate of population intake (*e.g.*, Dodd et al, 2006; Tooze et al., 2006). Even if the recalls are considered unbiased, uncertainty remains about using a limited number of short-term, cross-sectional data ('snapshots in time') to estimate long-term daily consumption rates (*e.g.*, Dodd et al., 2006; Tooze et al., 2006). While the 1994-1996 and 1998 CSFII collects survey data over two days, this does not necessarily depict "usual intakes" (U.S. EPA, 2004).

As described by U.S. EPA (2004), the 1994-1996 and 1998 multistage survey design does not support interval estimates for many of the subpopulations reported.[8] The survey design also does not support individuals who live in hot climates, who consume large amounts of water because of physical activity, and individuals with medical conditions necessitating increased water intake (U.S. EPA, 2004).

Based on the evaluation of the 2003-2004 and 2005-2006 NHANES WWEIA data (U.S. CDC, 2010 a,b), the biggest difference between the types and amount of water consumed currently and the types and amount of water consumed at the time of the CSFII 1994-96 and 1998 surveys may be found in bottled water. However, if the concern is exposure to lead in drinking water derived from the site, bottled water may not be a concern (*i.e.*, the community water consumption rates recommended in this report do not include bottled water).

RECOMMENDATIONS FOR THE IEUBK MODEL

The primary limitation of the current default water consumption rates in the IEUBK model is the representativeness of the survey data used to estimate water consumption. With approximately 20,000 and 30,000 participants in the 1976-1980 NHANES (U.S. DHHS, 1983) and the 1977-1978 NFCS (USDA, 1984), respectively, the current default values in the IEUBK model are considered sufficient for most young people, but do not reflect the increase in the consumption of direct (*e.g.*, soft drinks, bottled water) and indirect sources of water over the last three decades.

U.S. EPA (2011, 2010, 2009, 2008) identified Kahn and Stralka (2009) as a potential source for alternative water consumption values for children in the United States. Kahn and Stralka (2009) derived mean and percentile estimates of age-specific, daily average water consumption rates from the 1994-96 and 1998 CSFII (USDA, 2000). They calculated both indirect and direct water consumption for two water source categories: *"All Water Sources"* including water from all supply sources (*e.g.*, municipal tap, private well, bottled, other sources) and "*Community Water*" including tap water from a community or municipal water supply[9]. Kahn and Stralka (2009) further divided these two categories into two subcategories: *"All Individuals,"* including all participants (whether or not they ingested any water from the specified source during the 2-day survey) and *"Consumers Only,"* which excludes those who did not drink community water during the survey.

The Exposure Factors Handbook (U.S. EPA, 2011) recommended consumption rates are based on the analysis of the 1994-1996 and 1998 CSFII performed by Kahn and Stralka (2009). More specifically, the EFH recommended the consumption rates estimated for direct and indirect "*Community Water*" sources (ml/person/day) for "*All Individuals*" and "*Consumers Only*".

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[8] The CSFII 1994-96 and 1998 does not identify subpopulations (income level, ethnicity), while the NHANES survey does

[9] As described by Kahn and Stralka (2009), "direct water is water that survey respondents reported drinking directly as a beverage. Indirect water is defined as water added to foods or beverages during final preparation at home or by local food service establishments such as school cafeterias and restaurants. CSFII recipe files served as the basis for determining the percentage of indirect water contained per 100 g of each food consumed by participants. This percentage was then multiplied by the amount of food consumed by the survey respondents to determine the amount of indirect water ingested." Kahn and Stralka (2009) as noted that indirect water does not include intrinsic (i.e., the water naturally found in foods such as fruits and vegetables) and commercial water added to foods and beverages by the manufacturer prior to distribution.

The TRW also recommends the analysis of the 1994-1996 and 1998 CSFII performed by Kahn and Stralka (2009); however, the TRW recommends using the estimated direct and indirect total water consumption for "*All Water Sources*" for "*Consumers Only*". The grouping of "*All Water Sources*" takes into account the full use of the water resource, and that families that choose to use groundwater or community water for mixing formulas, juice, or soup and that choose not to drink bottled water will still be protected with these values. Also, estimates for *"Consumers Only"* are often the primary focus in analyses of risk due to ingestion of water that may be contaminated (Kahn and Stralka, 2009). Also, this is a health-protective exposure assumption, appropriate for risk assessment.

The TRW elected to use the consumption rate estimates by Kahn And Stralka (2009) over the 2003-04 and 2005-06 NHANES WWEIA because the 1994-1996 and 1998 CSFII database: a) included more survey participants, b) received a high level of peer review (U.S. EPA, 2011, 2010), and c) the sources of uncertainty were minimal (U.S. EPA, 2009). Feedback from Regional risk assessors also indicated that regional and ethnic information are not useful because populations move between regions and exposure is not typically ethnically homogenous. The TRW does not believe there is sufficient information for all lead exposure and biokinetic variables, nor is there necessarily a need, to model sex-specific information for typical Superfund site-specific risk assessments.

The recommended values are based on national averages; however, these values may not necessarily represent subpopulations of children that may have higher exposure (*e.g.*, due to cultural practices, diets heavy in canned foods, or those who live in hot climates). The IEUBK model will continue to allow for input of site-specific water consumption information as shown in Figure 1.

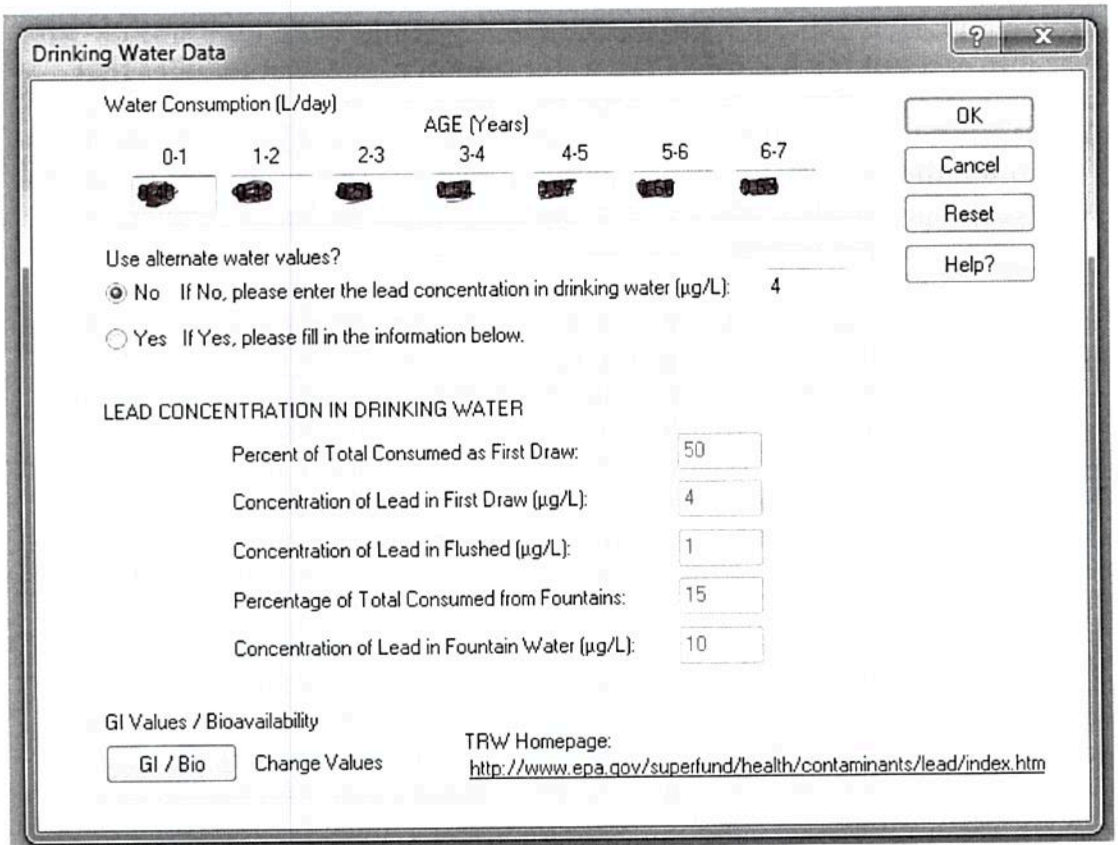

Figure 1. Proposed *Water Consumption* default values shown in the IEUBK model Drinking Water Window.

IMPACT ON THE IEUBK MODEL PREDICTIONS

Using current IEUBK model defaults for all other parameters while implementing the recommended water consumption rates will increase the GM PbB for children (0-7 years of age) from 2.730 µg Pb/dL to [redacted] µg/dL. Table 5 presents the updated estimates. As shown in Table 5, the recommended changes do not have a significant impact on the probability of the geometric mean exceeding 10 µg/dL nor do they impact PRGs in the soil lead concentration range (in the interest for OSRTI).

Table 5. Effects of changing the water consumption variable in the IEUBK model

Source	Age Range (months)							GM	P_{10}	PRG for 5% NTE 5 µg/dL	PRG for 5% NTE 10 µg/dL
	0 < 12	12 < 24	24 < 36	36 < 48	48 < 60	60 < 72	72 < 84				
IEUBK Model Default Value[a]											
Consumption Rate (L/day)	0.2	0.5	0.52	0.53	0.55	0.58	0.59	2.730	0.287	153	418
Lead Uptake from Water (µg/day)	0.375	0.929	0.976	1.004	1.059	1.123	1.146				
Calculated Total Lead Uptake (µg/day)	5.586	8.368	8.593	8.651	7.045	6.720	6.592				
Calculated Blood Lead Concentration (µg/dL)	3.0	3.5	3.2	3.0	2.5	2.1	1.9				
Proposed IEUBK Model Default Value[b]											
Consumption Rate (L/day)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Lead Uptake from Water (µg/day)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]				
Calculated Total Lead Uptake (µg/day)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]				
Calculated Blood Lead Concentration (µg/dL)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]				

GM: Geometric mean blood lead concentration (µg/dL) for 0-84 month age range; NTE: Not to Exceed; P10: Probability of the predicted GM blood lead concentration ≤ 10 µg/dL; PRG: preliminary remediation goal; NTE: not to exceed

[a] IEUBK Model (v. 1.1, build 11)

[b] Kahn and Stralka, 2009; all water sources, consumers only

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